Universities: The Fallen Angels of Bayh-Dole?

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Abstract: The Bayh-Dole Act of 1980 established a new default rule that allowed nonprofit organizations and small businesses to own, as a routine matter, patents on inventions resulting from research sponsored by the federal government. Although universities helped get the Bayh-Dole Act through Congress, the primary goal, as reflected in the recitals at the beginning of the new statute, was not to benefit universities but to promote the commercial development and utilization of federally funded inventions. In the years since the passage of the Bayh-Dole Act, universities seem to have lost sight of this distinction. Their behavior as patent seekers, patent enforcers, and patent policy stakeholders often seems to work against the commercialization goals of the Bayh-Dole Act and is difficult to explain or justify on any basis other than the pursuit of revenue.

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The Bayh-Dole Act of 1980 established a new default rule that allowed nonprofit organizations and small businesses to own, as a routine matter, patents on inventions resulting from research sponsored by the federal government.[1] The new law replaced divergent and changeable rules and practices of different federal funding agencies. It made ownership more predictable and reduced the need for case-by-case negotiations to secure rights.[2]

University patent ownership featured prominently in subsequent commentary on the Bayh-Dole Act, but the initial choice to limit the new rule to nonprofit organizations and small businesses was a matter of political expediency. Although universities helped get the Bayh-Dole Act through Congress, the primary goal, as reflected in the recitals at the beginning of the statute, was not to benefit universities but to promote the commercial development and utilization of federally funded inventions.[3] It was part of a broader initiative to give patent ownership to research contractors, rather than to federal funding agencies, in order to accelerate commercial development. By ap-

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plying the new default ownership rule only to nonprofit organizations (including universities) and small businesses, advocates sidestepped decades-old objections to giving patent monopolies to powerful business interests when inventions were made at taxpayer expense. Had large businesses been included in Bayh-Dole, an anonymous Senate aide confided to a reporter, "the bill would never have [had] a chance of passing."[4] But the limitation was only temporary. Soon enough, the new policy was extended to large businesses, first quietly in an executive order signed by President Ronald Reagan, and then more durably in an inconspicuous amendment to the statute.[5]

Universities fit awkwardly in the arguments for patent ownership by contractors rather than government agencies. Advocates emphasized that government agencies do not commercialize inventions themselves, and therefore government ownership inevitably required costly licensing transactions to transfer the rights that firms required to protect investments in commercialization. Government stewards might be cautious about giving public property away to private firms, introducing uncertainty and delay. When the contractor was a private firm, commercialization could proceed more quickly by vesting rights in the contractor from the outset. But universities are quite different from private firms. Like the government, universities do not themselves commercialize inventions, but must license their patents for commercialization to proceed. Moreover, in 1980, most universities were relative newcomers to the patent system, having generally avoided patenting for much of the twentieth century, concerned that patenting conflicted with their mission to disseminate knowledge.[6] Universities had no more, and arguably less, expertise in licensing than the government agencies that were criticized as ineffective, and had a similar history of hostility toward patents.

Universities had, however, another argument for patent ownership: only they could provide the close collaboration between faculty and commercial licensees necessary to achieve effective technology transfer for early-stage inventions made in academic laboratories. Patent ownership would give universities and their faculties incentives to secure patent rights and to aid commercial licensees in developing their inventions and bringing them to market. Otherwise, universities would have little reason to divert time and resources away from their academic missions in order to secure patents and to collaborate with licensees. Universities' history of forsaking patents in favor of publication and the dissemination of knowledge made this account plausible. It also made universities seem more trustworthy than business firms: universities would use their patents for public benefit rather than private gain. The perceived halos over universities lit the path to passage of the Bayh-Dole Act.

As a justification for university patents, the logic of technology transfer has limits. Some university inventions surely fit the paradigm of early-stage discoveries requiring further substantial private investment, assisted by university scientists, to launch as commercial products. An important example highlighted in the Bayh-Dole hearings was candidate drugs funded by the National Institutes of Health (NIH) medicinal chemistry program. Private firms had proven unwilling to develop these drugs and to shepherd them through the FDA approval process under the terms of NIH agreements from the 1960s that restricted the firms' ability to secure exclusive rights.[7] Exclusive patent rights were necessary to motivate pharmaceutical firms to invest in expensive clinical trials of promising new drugs. The NIH responded by developing Institutional Patent Agreements (IPAs) that enabled universities to patent drugs resulting from federally funded re-

search and to license their rights to firms. But some IPAs were stalled in administrative review while Bayh-Dole was pending, fueling university interest in codifying patent ownership rules.

Many university inventions, however, do not require substantial postdiscovery investment and the assistance of faculty inventors to achieve commercial application. Some of the most lucrative university patents covered broad enabling technologies that would have been ready for widespread use with or without university patents. These included the Cohen-Boyer patents on basic recombinant DNA techniques (which have generated approximately $255 million for Stanford University and the University of California) and the Axel patents on methods to introduce genes for foreign proteins in eukaryotes (which have generated approximately $800 million for Columbia University).[8] Such technologies face little risk of languishing in academic archives if they are published without patents. Patenting them may provide revenue for universities, but it does not further Bayh-Dole's explicit goal of promoting the development and dissemination of new technologies. According to Niels Reimers, who developed the licensing scheme for the Cohen-Boyer patents, patents on such platform technologies impose a "tax" on subsequent applications, redounding to the benefit of universities, which then use the funds for education and research.[9] Universities prize such patents as a source of unfettered discretionary funds, but they do not promote commercialization; rather, they make commercial development more costly by imposing a need to negotiate and pay for licenses.

Congress recognized that contractor ownership might not be the best way to achieve its goals in all cases. Bayh-Dole provided several mechanisms to depart from this default rule in the terms of funding agreements. In "exceptional circumstances," the agency could determine that withholding title to the invention would better promote the goals of the Act.[10] An agency could also exercise statutory "march-in rights" to license Bayh-Dole patents if it determined that the university or its exclusive licensee was not taking steps to achieve "practical application of the subject invention" or, if necessary, "to alleviate public health or safety needs."[11] Finally, the government retained a paid-up, nonexclusive license to use or to authorize others to use the inventions on behalf of the government.[12] But federal research sponsors have made little use of these provisions to date, perhaps because of burdensome procedural requirements.[13] These requirements were no accident. The architects of Bayh-Dole sought to overcome hostility toward patents in universities and in some funding agencies that they saw as an obstacle to commercial development.

The statute did not limit the new ownership rule to inventions requiring follow-on investment to promote development. And universities have not imposed such limits on themselves.[14] Universities soon came to regard their Bayh-Dole patents as entitlements, using them to generate revenue even when licensing rights were unnecessary for commercialization. The result may actually impede commercialization in some cases, and certainly makes it more expensive.

The drafters of the Bayh-Dole Act may have failed to realize that antipatent attitudes were quickly declining in the academy. Bayh-Dole accelerated a trend that was well under way in the 1970s to reverse formal policies against patenting and to establish university technology transfer offices.[15] As economist Bhaven Sampat observes, Bayh-Dole fostered university patenting "by providing strong Congressional endorsement for the position that active university involvement in patenting and licensing, far from being ignoble, serves the public interest."[16] Perhaps universities could keep their halos while plow-

ing patent revenues back into research and education.

One could argue for university patent ownership as a way to give universities financial rewards for valuable inventions. Notably, this is not among the seven goals recited in the Bayh-Dole preamble.[17] Such an explicit recital might well have drawn political fire. But the argument was not even made.

Sometimes legislation enacted for one purpose turns out to serve another, equally important purpose. Whatever the intent in 1980, enhancing university revenues through patents may now seem like sound policy. But even now, the revenue-for-universities rationale is raised only *sotto voce*, if at all. In case after case, universities justify their patent rights by appealing to the danger of inventions languishing for lack of patent protection, even when university patents are plainly unnecessary for commercialization. The argument persists because promoting commercialization, not revenue, was the foremost justification for university patent ownership in the Bayh-Dole Act.

The overall impact of Bayh-Dole has been a topic of lively debate in the thirty-eight years since its passage.[18] University patenting has dramatically increased, and a few universities have made a lot of money from royalties. Yet licensing revenues remain a small portion of university budgets overall. Respondents to a 2015 survey of the Association of University Technology Managers reported $2.5 billion in licensing revenues (including revenues from trademark, copyright, and unpatented technologies). This is less than 4 percent of the $66.6 billion in university research expenditures, with the wealthiest universities capturing most of the benefits. Although university technology transfer professionals take credit for stimulating commercial development of new technologies, it is not clear how much of that development would have occurred without university patents.

In the post–Bayh-Dole era, universities – the third-largest employer of lobbyists – have had some success in getting Congress to shape patent law to favor their interests.[19] They have secured statutory changes that fortify university patents and make it harder for firms to avoid liability for infringing them.

Meanwhile, universities have had important losses in the courts, especially before the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), an intermediate appellate court with consolidated jurisdiction over patent matters. In a growing body of case law, the courts have refused to adapt patent doctrine to accommodate the circumstances of university research, sometimes with open skepticism toward arguments that universities are acting in the public interest. At times, special pleading from universities seems to have backfired, provoking courts to fortify doctrines that limit the patenting of the kinds of early-stage discoveries that universities often produce.

Universities have, in many cases, pursued patents that they could enforce against product-developing firms for the evident purpose of getting a piece of the action in lucrative technologies that were already being actively developed without the need for university patents. They have sometimes worn their academic halos to court, seeking to adapt patent doctrine to privilege the interests of universities over the competing interests of product-developing firms. This agenda has met with considerable skepticism from the Federal Circuit, which has sometimes explicitly questioned whether university patents are promoting or impeding commercial product development.

An early sign that universities were pursuing patents that were unnecessary for commercial development was the involvement of universities in interference proceedings – administrative proceedings within

the U.S. Patent and Trademark Office to determine priority of invention – in which the university claimed to have made the invention before a commercial inventor. When a university competes with a near-simultaneous commercial inventor seeking patent rights on the same invention, it is difficult to argue that the university is just trying to preserve incentives for commercialization of an invention that would otherwise fail to attract commercial interest. Interferences are only available to establish priority for patent applications filed before March 16, 2013, when U.S. law changed to award priority to the first inventor to file a patent application rather than to the first to make the invention.[20] But before that date, interferences were especially common in biotechnology, a field in which multiple research teams often compete intensely to reach the same goals (such as cloning an obviously important gene). Health policy scholars Jonathan Merz and Michelle Henry found that interferences in biotechnology and organic chemistry were six times more frequent than for patents on average, and that most of the highly competitive "races" the authors cited involved academic research institutions.[21]

Having to litigate a costly interference against a university can only increase the costs and risks facing a product-developing firm. Yet universities persisted in these costly battles, appealing to the Federal Circuit when they lost in the Patent Office. In a priority dispute between academic patent applicants and a pharmaceutical firm over an assay to identify anticancer compounds, for example, the University of Texas Southwestern Medical School pursued repeated appeals to the Federal Circuit, although presumably the firm's commercialization incentives would have been adequately protected by its own already-issued patent on the same invention.[22]

Another strategy for universities more interested in revenues than in promoting product development is to seek broad patent rights on the basis of preliminary academic research that would allow them to sue private firms that later develop products not disclosed in the university patent applications. The Federal Circuit has been consistently hostile to these efforts, invalidating university patents in a series of decisions that fortified the patent law requirement that a patent application must include a "written description" of the invention.[23]

Regents of the University of California v. Eli Lilly involved the first commercial recombinant DNA product that ever reached the market: human insulin.[24] University of California (UC) researchers, having cloned the rat insulin gene, obtained a broad patent covering recombinant microorganisms with DNA sequences encoding human insulin, mammalian insulin, and vertebrate insulin, although the only sequence they disclosed was for rat insulin.[25] Meanwhile, scientists at Genentech successfully cloned the human insulin gene and produced recombinant human insulin. The pharmaceutical firm Eli Lilly manufactured and distributed the final product, which began to replace the previously used insulin product purified from slaughtered pigs as a treatment for diabetes. The University of California sued Eli Lilly and Genentech for patent infringement. On appeal, the Federal Circuit held the UC patent invalid on the basis of what was then a controversial application of the written description requirement. The Federal Circuit held that the written description in the UC patent disclosure only showed possession of the gene for rat insulin, and because the human insulin gene had a slightly different DNA sequence (because the human insulin protein has a somewhat different amino acid sequence), the patent disclosure was insufficient to support the claims to genes for human insulin and for all vertebrate and mammalian insulins. Eli Lilly and Genentech were therefore free to

market recombinant human insulin without liability to the University of California.

Later cases used the invigorated written description requirement to invalidate broad university patent claims to methods of treatment based on discoveries of metabolic pathways likely to be useful in developing new drugs. In *University of Rochester v. G. D. Searle*, the Federal Circuit invalidated claims that would have allowed the University of Rochester to demand royalties from pharmaceutical firms that had developed any selective Cox-2 inhibitors.[26] Cox-2 inhibitors are anti-inflammatory drugs with fewer gastrointestinal side effects than aspirin.[27] The Federal Circuit invalidated the university's patent on a "method for selectively inhibiting PGHS-2 activity in a human host" for lack of an adequate written description. The inventors developed an assay to identify Cox-2 inhibitors, but did not identify or describe any specific inhibitors. The court explicitly rejected the argument that this holding "will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector," noting that "none of the…policy objectives of the Bayh-Dole Act encourages or condones less stringent application of the patent laws to universities than to other entities."[28]

The Federal Circuit was even more emphatic in its *en banc* decision in *Ariad Pharmaceuticals v. Eli Lilly*.[29] Researchers at Harvard and the Massachusetts Institute of Technology (MIT) described the NFκB pathway that explained the mechanisms of action of several blockbuster drugs. As in the Rochester case, the university researchers had not actually found an inhibitory compound, but their patents broadly claimed methods of regulating NFκB activity. The Harvard/MIT patents were licensed exclusively to Ariad Pharmaceuticals, which sued Eli Lilly, developer of the NFκB inhibitors Evista and Xigris. The Federal Circuit seemed to view the university patents as anticipatory poaching of the work of the pharmaceutical industry rather than as essential enablers of commercialization:

> Such claims merely recite a description of the problem to be solved while claiming all solutions to it…leaving it to the pharmaceutical industry to complete an unfinished invention. Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the "useful Arts," U.S. Const. art. I, §8, cl. 8, meaning inventions with a practical use . . . and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention.…[The law] limits patent protection to those who actually perform the difficult work of "invention" – that is, conceive of the complete and final invention with all its claimed limitations – and disclose the fruits of that effort to the public.[30]

The Federal Circuit rejected arguments that the "written description" doctrine that it had used to invalidate this and other broad university patents on early-stage discoveries removed incentives for private investment in the commercialization of university inventions. Perhaps these arguments seemed particularly unpersuasive in a lawsuit against a firm that had developed and brought to market two commercial products without the benefit of any protection provided by the university patents.

The practical significance of this line of cases has been partially eclipsed by more recent decisions from the U.S. Supreme Court limiting patentable subject matter. These decisions, which preclude patents on natural products, laws of nature, and phenomena of nature, provide an alternative basis for invalidating university pat-

ents arising from fundamental discoveries about biochemical pathways.[31] Universities participated in *amicus* briefs that unsuccessfully argued against the approach ultimately taken by the Court. The Supreme Court holdings extend beyond the problem of reach-through patents from universities – the cases that gave rise to the robust written description requirement from the Federal Circuit – and call into question the validity of many commercial patents in the life sciences.[32]

Yet both the Federal Circuit's written description requirement and the Supreme Court's patentable subject matter doctrine reflect similar concerns: that broad patents on early research discoveries might hinder science and impede rather than promote applications of those discoveries. Although both written description and patentable subject matter doctrines apply to all patents, they present more of an obstacle to patenting early stage research discoveries from university laboratories than to patenting commercial products. Universities argued that these consequences contravened the purposes of the Bayh-Dole Act, but to no avail. These decisions thus represent significant losses for universities and provide a countervailing narrative to the story that university patents are necessary for commercial development.

In addition to seeking patents that are not necessary to promote commercialization, universities have put revenue goals ahead of commercialization by enforcing their patents in litigation against firms that have already developed successful commercial products without the benefit of university patents.[33]

A recent example that reached the U.S. Supreme Court is *Stanford University v. Roche Molecular Systems*.[34] The patents at issue arose from NIH-funded research performed by Mark Holodniy, a Stanford postdoctoral fellow. Stanford researchers were collaborating with scientists at the private firm Cetus to develop an HIV assay using the polymerase chain reaction (PCR). PCR is an important technology developed at Cetus that later won its inventor, Kary Mullis, a Nobel Prize. Stanford sent Holodniy to Cetus to learn PCR and to work on an HIV assay. Holodniy then returned to Stanford and tested the assay in the clinic with other Stanford inventors before Stanford filed patent applications. Meanwhile, Roche acquired Cetus's PCR patent rights and began manufacturing PCR-based HIV detection kits. After the patents were issued to Stanford, Stanford sought royalties from Roche. When they failed to reach agreement, Stanford sued Roche for patent infringement. On appeal, the Federal Circuit ruled that Roche, rather than Stanford, was the true owner of Holodniy's interest in the patents based upon its technical analysis of the legal effects of the terms of two different agreements: a "Visitor Confidentiality Agreement" that Holodniy signed at Cetus and a "Copyright and Patent Agreement" that he had previously signed at Stanford.[35] The Supreme Court granted review to consider whether the Bayh-Dole Act required a different result.[36]

Stanford made a compelling argument that allocation of ownership to Cetus/Roche contravened the design of the Bayh-Dole Act to give universities (and other contractors) the first option to claim rights in inventions made in federally sponsored research. As Justice Breyer explained in a dissenting opinion, contractor ownership is necessary to ensure compliance with a set of conditions that the Bayh-Dole Act requires be included in research funding agreements to protect the public interest.[37] These include provisions for retention of government licenses, reporting obligations, and restrictions on permissible assignments. These safeguards are lost when inventions are assigned – even inadvertently, as apparently happened in this

case – to third parties not bound by those agreements. Moreover, the Bayh-Dole Act contemplates a clear hierarchy of claims to patent ownership with the contractor first in line, followed by the sponsor, and with inventors allowed to claim ownership only when neither the contractor nor the sponsor objects.[38] Justice Roberts's majority opinion inverts this order by holding that the Bayh-Dole Act applies only to inventions owned by the contractor, and not to inventions that employees fail to assign properly to contractors. Although the majority opinion purports to apply strict textual analysis to the language of the Bayh-Dole Act, it ignores many textual cues about the design of the statute that support a different interpretation.

On the other hand, it is hard to argue that Stanford's assertion of patent rights promoted commercialization. Roche developed the technology commercially years before Stanford's patents issued. Roche clearly did not rely on Stanford's patents. The patents did not help Roche, but rather gave Stanford an opportunity to claim a share of the proceeds.

Hard cases make bad law. To the extent that *Stanford v. Roche* calls into question whether universities hold secure title to the patents they are trying to license, it jeopardizes the commercialization goals of the Bayh-Dole Act as well as the protections for the public interest that the Bayh-Dole Act addresses in the terms of funding agreements. Stanford's overreaching in this particular case, where university patents were unnecessary for commercialization, may threaten future rights where clear university title is essential for further development.

In 2008, intellectual property law scholar Mark Lemley posed the provocative question, "are universities patent trolls?"[39] The idea that universities can be patent trolls (that is, patent assertion entities that do not themselves commercialize technology but profit by asserting patents against commercial firms) soon became more commonplace, as major research universities used their patents to collect hundreds of millions of dollars in damage awards and settlements.[40] Criticized for behaving like patent trolls, universities have sometimes sought to avoid the reputational costs of litigation by selling their rights to undisputed patent trolls.[41]

Like patent assertion entities, universities can enforce their patents with little fear of provoking counterclaims for infringement of the patents held by the defendants. Patent infringement litigation against universities and academic researchers is quite rare. This allows university scientists to infringe patents in their laboratories with relative impunity even as universities enforce their patents against other institutions.[42] But this is largely the result of forbearance by patent owners rather than legal immunity from suit.

Universities lost a claim to special status as infringement defendants in the case of *Madey v. Duke University*.[43] Physicist John Madey sued Duke for using his patented field electron laser in a university laboratory. Rejecting Duke's argument that the noncommercial character of academic work precludes infringement liability, the Federal Circuit held that the university would be liable for any use that was in keeping with the "legitimate business" of the university:

> For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students, and faculty.[44]

In a footnote, the court added that "Duke …like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream."[45] In other words, to the Federal Circuit, universities are not angels entitled to a privileged status in the patent system, but rather a particular kind of worldly institution pursuing its own objectives, including money.

Other academics may have more to gain than commercial firms from suing academic institutions for patent infringement. Indeed, *Madey v. Duke* was a lawsuit brought by a faculty member against his former university. In another currently pending case, the University of South Florida has sued both the NIH and the nonprofit Jackson Laboratories for making and distributing transgenic mice that are used in Alzheimer's disease research.[46] The cases may or may not succeed, but the fact that a university would bring these lawsuits suggests a decline of academic sharing norms as universities seek to profit from their patents.

Universities have also sought to expand their patent rights by lobbying Congress to change the patent laws in their favor, with mixed results.

This strategy backfired in a campaign by Columbia University to extend the term of its lucrative Axel patents. Columbia worked through Senator Judd Gregg of New Hampshire, a Columbia alumnus, who introduced three different bills in an attempt to extend Columbia's patent term.[47] The patents were then under license to multiple commercial firms, none of which stood to benefit by prolonging their royalty obligations to Columbia. When Senator Gregg's backroom legislative maneuvers became public, there was a strong backlash against both him and Columbia from drug manufacturers, consumer groups, and other members of Congress. Senator Gregg responded that Columbia was "a poor little university" contending with "a fair amount of greed on the part of the drug companies."[48] This phrase came back to haunt Columbia when some of its licensees sued to invalidate one of Columbia's patents. During a hearing in that case, the District Court judge, observing eight lawyers for Columbia in his courtroom, quipped "I thought Columbia was a nonprofit organization who couldn't afford this litigation."[49] In 2004, Columbia signed covenants not to sue the companies for infringement of the disputed patent, and later that year further agreed not to sue anyone else and backed away from demanding royalties.[50]

Other university lobbying efforts have been more successful, leading to statutory changes that make it easier for universities to obtain and enforce patents.[51] Some of these moves have been broadly congruent with the goals of the Bayh-Dole Act. The CREATE Act of 2004, for example, facilitates university-industry research collaborations by extending the benefit of a statutory safe harbor that, as originally enacted, prevented the use of nonpublic information as patent-defeating prior art against patent applications filed by other employees within the same firm.[52] As amended by the CREATE Act, the safe harbor also applies to information belonging to another party to a joint research agreement.[53] This is consistent with the objectives of the Bayh-Dole Act. The recitals in the Bayh-Dole Act reflect a clear intent "to promote collaboration between commercial concerns and nonprofit organizations, including universities," and the statutory change facilitates such interactions by allowing free communication in the course of such collaborations without fear of losing patent rights.[54]

Universities had a significant impact on the new first-to-file rules in the America Invents Act of 2011 (AIA). That legislation changed U.S. law to conform to patent laws of other countries by shifting from the in-

vention date to the application filing date as the time for determining whether an invention is patentable in light of the prior art. Universities initially opposed this change. They worried that the first-to-file priority rule might force them to incur substantial patent filing costs to preserve priority, and that scientists would be unwilling to defer publication until after patent filing.[55] In the end, universities persuaded Congress to modify the new rule to retain a modified version of a one-year "grace period" from prior U.S. law.[56] The grace period gives inventors a year after public disclosure before they lose the right to file patent applications.

Although the grace period is formally available to all inventors, it is most likely to benefit universities. Commercial firms that plan to seek patent rights in other countries are unlikely to rely on it, because public disclosures in the United States would defeat their patent rights elsewhere. But to the extent that it facilitates early publication of research results, the grace period may encourage prompt dissemination of new knowledge.

It is harder to identify a public policy argument, however, for changes that universities secured to a "prior user" infringement defense in the AIA. Like the modified grace period, this provision grew out of university resistance to a proposed change in the law. In 1999, following unexpected decisions of the Federal Circuit upholding patents on methods of doing business, Congress enacted a new "prior user" infringement defense, initially available only against business method patents.[57] This defense protected a user who, acting in good faith, completed the invention at least one year before the patent filing date and commercially used it before the filing date.

The AIA expanded the prior user defense in several ways. It broadened it to cover all patents, not just patents on business methods.[58] It extended the defense to certain related parties and assignees of the original prior user. And although it retained the language about "commercial use," in a bow to universities, it added a new provision defining commercial use to include "use by a nonprofit laboratory or other nonprofit entity such as a university or hospital, for which the public is the intended beneficiary." So far so good: expanding the prior user defense to include universities was entirely consistent with the goals of Bayh-Dole.

More troubling, however, was a change that effectively eliminated prior user rights as a defense to infringement of university patents. In response to university lobbying, Congress added the so-called university exception. Under that exception, a defendant may *not* invoke the prior user defense if the invention "was, at the time the invention was made, owned or subject to an obligation of assignment to . . . an institution of higher education."[59] In other words, when universities are sued as infringement defendants, they can invoke prior user rights to avoid liability, but when universities assert their patents against others, prior user rights are unavailable to defendants. This turns the commercialization justification for the Bayh-Dole Act upside down. Rather than using their patents to help commercial firms develop early stage academic inventions into useful products, universities (and only universities) may now use their patents to sue firms that are so far ahead of academic scientists that they had already put the invention to commercial use a full year before the university filed a patent application. Moreover, since the "university exception" turns not on current ownership, but on whether there was an obligation to assign at the time the invention was made, the defense remains unavailable even if the university later sells the patent to a patent assertion entity (that is, a patent troll).

The statutory text shows vestigial remnants of a university halo. The expansion

of the prior user defense to university laboratories includes the qualification that the use be one "for which the public is the intended beneficiary."[60] But universities tarnished their halos by persuading Congress to eliminate prior user rights as a defense against university patents.

These successes in getting Congress to give universities special treatment under patent law show that the university technology transfer community has become a force to be reckoned with in patent policy. But they also show universities using their lobbying muscle in unabashed pursuit of their own financial interests rather than broader public interests in the dissemination and utilization of new knowledge.

The Bayh-Dole Act chose universities and small businesses as the first beneficiaries of a broader policy shift that aimed to facilitate the commercialization of inventions made in the course of government-sponsored research. It allocated ownership of patent rights to contractors rather than to government funding agencies. Universities, as traditional champions of free dissemination of new knowledge, were regarded as trustworthy stewards of patent rights for the public benefit, in contrast to the big business contractors who later benefited from the same policy. The focus on universities and small businesses made it easier to pass the legislation. Nonetheless, the clear goal of the Bayh-Dole Act was not to generate revenues for universities on government-sponsored research, but rather to facilitate commercial development of new technologies that needed patent incentives to induce postdiscovery private investment.

In the years since passage of the Bayh-Dole Act, universities seem to have lost sight of this distinction. Their behavior as patent seekers, patent enforcers, and patent policy stakeholders often seems to work against the commercialization goals of the Bayh-Dole Act and is difficult to explain or justify on any basis other than the pursuit of revenue.

Universities do good work, and more revenue allows them to do more of it. But revenues from university-owned patents remain a small source of revenue for universities overall, and in total account for less than 5 percent of universities' research expenditures. The policy question is: when do the benefits of university patents justify the costs? Meanwhile, technology transfer offices, as opposed to faculty, have come to dominate the voice of universities in debates about patent policy. The result is a tail-wagging-the-dog distortion, in which the interests of universities as patent owners may be overwhelming their broader interests in widespread dissemination and utilization of new knowledge for the public benefit.

ENDNOTES

[1] Act of December 12, 1980, Pub. L. No. 960517, 94 Stat. 3015-28, codified as amended in pertinent part at 35 U.S.C. §§ 200 – 211 [commonly known as the Bayh-Dole Act].

[2] Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review* 82 (1996): 1663 – 1727.

[3] 35 U.S.C. § 200.

[4] William J. Broad, "Patent Bill Returns Bright Idea to Inventor," *Science* 205 (1979): 473 – 476.

[5] Ronald Reagan, "Memorandum on Government Patent Policy," Memorandum to the Heads of Executive Departments and Agencies, Pub. Papers 248, February 18, 1983; and Trademark

Clarification Act of 1984 § 501(13), Pub. L. No. 989-620, 98 Stat. 3367, codified as amended at 35 U.S.C. § 210(c).

[6] Bhaven N. Sampat, "Patenting and U.S. Academic Research in the 20th Century: The World before and after Bayh-Dole," *Research Policy* 35 (6) (2006): 772 – 789.

[7] Harbridge House, Government Patent Policy Study, *Final Report for the FCST Committee on Government Patent Policy* (Boston: Harbridge House, Inc., 1968), 2 – 40, discussed in Eisenberg, "Public Research and Private Development," 1682 – 1684 [see note 2].

[8] National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington, D.C.: The National Academies Press, 1997), 40 – 42; and Alessandra Colaianni and Robert Cook-Deegan, "Columbia University's Axel Patents: Technology Transfer and Implications for the Bayh-Dole Act," *Milbank Quarterly* 87 (3) (2009): 683 – 715.

[9] Niels Reimers, "Tiger by the Tail," *Chemtech* 17 (1987): 464 – 471.

[10] 35 U.S.C. § 202(a).

[11] 35 U.S.C. § 203(1)(a) – (c).

[12] 35 U.S.C. § 202(c)(4).

[13] Arti K. Rai and Rebecca S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *Law and Contemporary Problems* 66 (2003): 289 – 314; and Barbara M. McGarey and Annette C. Leavey, "Patents, Products & Public Health: An Analysis of the Cell Pro March-In Petition," *Berkeley Technology Law Journal* 14 (1999): 1095 – 1116.

[14] Ian Ayres and Lisa Larrimore Ouellette, "A Market Test for Bayh-Dole Patents," *Cornell Law Review* 102 (2017): 271 – 331.

[15] David C. Mowery, Richard R. Nelson, Bhanven N. Sampat, and Arvids Ziedonis, "The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980," *Research Policy* 30 (2001): 99 – 119; Elizabeth Popp Berman, "Why Did Universities Start Patenting?" *Social Studies of Science* 38 (6) (2008): 835 – 871; and Elizabeth Popp Berman, *Creating the Market University: How Academic Science Became an Economic Engine* (Princeton, N.J.: Princeton University Press, 2012).

[16] Sampat, "Patenting and U.S. Academic Research in the 20th Century," 776 [see note 6].

[17] "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area." Act of December 12, 1980, § 200 [see note 1].

[18] For a thoughtful review and synthesis of the literature, see Rochelle Cooper Dreyfuss, "Double or Nothing: Technology Transfer under the Bay-Dole Act," in *Business Innovation and the Law: Perspectives from Intellectual Property, Labour, Competition and Corporate Law*, ed. Marilyn Pittard, Ann L. Monotti, and John Duns (Cheltenham, United Kingdom: Edward Elgar, 2013), 52 – 73.

[19] Brody Mullins, Douglas Belkin, and Andrea Fuller, "Colleges Flex Lobbying Muscle," *The Wall Street Journal*, November 8, 2015.

[20] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, codified as amended in pertinent part at 35 U.S.C. §§ 102, 103. See U.S. Patent and Trademark Office, *Manual of Patent Examination Procedures* (MPEP) § 2159.

[21] John F. Merz and Michelle R. Henry, "The Prevalence of Patent Interferences in Gene Technology," *Nature Biotechnology* 22 (2004): 153–154.

[22] *Brown v. Barbacid*, 276 F.3d 1327 (Fed. Cir. 2002); *Brown v. Barbacid*, 436 F.3d 1376 (Fed. Cir. 2006); and U.S. Patent No. 5,185,248.

[23] 35 U.S.C. § 112.

[24] 119 F.3d 1559 (Fed. Cir. 1997).

[25] U.S. Patent No. 4,652,525. Rat insulin has one more amino acid than human insulin and is not biologically active in humans; indeed, it provokes an immune response.

[26] 358 F.3d 916 (Fed. Cir. 2004).

[27] U.S. Patent No. 6,048,850.

[28] 358 F.3d at 929.

[29] 598 F.3d 1336 (Fed. Cir. 2010).

[30] *Ariad v. Eli Lilly*, 598 F.3d at 1353. See also Pauline Newman, additional views, noting that the subject matter of the patent "is indeed basic research, which was taken to the patent system before its practical application was demonstrated." 598 F.3d, 1358.

[31] *Mayo Collaboration Services v. Prometheus Laboratories*, 566 U.S. 66 (2012); and *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013). See also *Bilski v. Kappos*, 561 U.S. 593 (2010); and *Alice v. CLS Bank*, 134 S. Ct. 2347 (2014) [reinvigorating traditional exclusion from patentable subject matter for abstract ideas].

[32] Rebecca S. Eisenberg, "Diagnostics Need Not Apply," *Journal of Science and Technology Law* 21 (2) (2015): 256–286.

[33] Jacob H. Rooksby, "University Initiation of Patent Infringement Litigation," *The John Marshall Review of Intellectual Property Law* 10 (623) (2011).

[34] 563 U.S. 776 (2011).

[35] 583 F.3d 832, 841–842 and 844 n. 1 (2009).

[36] 563 U.S. at 784 n. 2.

[37] 563 U.S. at 794.

[38] 35 U.S.C. § 202(d). "If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder."

[39] Mark A. Lemley, "Are Universities Patent Trolls?" *Fordham Intellectual Property, Media, and Entertainment Law Journal* 18 (611) (2008).

[40] Daniel Engber, "In Pursuit of Knowledge, and Profit: How Universities Aid and Abet Patent Trolls," *Slate*, May 7, 2014, http://www.slate.com/articles/technology/history_of_innovation/2014/05/patent_trolls_universities_sometimes_look_a_lot_like_trolls.html; and Andrew Chung, "Schools that Sue: Why More Universities File Patent Lawsuits," Reuters, September 15, 2015, http://www.reuters.com/article/university-patents-idUSL1N11G2C820150915.

[41] Chung, "Schools that Sue" [see note 40]; Walter D. Valdivia, "Patent Infringement Suits Have a Reputational Cost for Universities," TechTank blog, November 10, 2015, https://www.brookings.edu/blog/techtank/2015/11/10/patent-infringement-suits-have-a-reputational-cost-for-universities-2/; Andrew K. Cordova and Robin Feldman, "Universities and Patent Demands," *Journal of Law and Biosciences* 2 (3) (2015): 717–721; and Paul Basken, "Under Financial Pressure, Universities Give Patent Buyers a Closer Look," *Chronicle of Higher Education*, October 25, 2013, http://www.chronicle.com/article/Under-Financial-Pressure/142613/.

[42] For a review of empirical studies, see Rebecca S. Eisenberg, "Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research," *Houston Law Review* 45 (2008): 1059 – 1099.

[43] 307 F.3d 1351, cert. denied, 539 U.S. 958 (2003).

[44] Ibid., 1362.

[45] Ibid., 1362, n. 7.

[46] Frances McMorris, "USF Files Patent Suit in Dispute over Genetically Modified Mice," *Tampa Bay Business Journal*, December 23, 2015, http://www.bizjournals.com/tampabay/news/2015/12/23/usf-files-patent-suit-in-dispute-over-genetically.html.

[47] Colaianni and Cook-Deegan, "Columbia University's Axel Patents," 701 – 706 [see note 8].

[48] Paul Kane, "Hatch, Gregg Sparring over Patent for Columbia U," *Roll Call*, May 22, 2000.

[49] Bernard Wysocki Jr., "College Try: Columbia's Pursuit of Patent Riches Angers Companies," *The Wall Street Journal*, December 21, 2004.

[50] Colaianni and Cook-Deegan, "Columbia University's Axel Patents," 705 [see note 8].

[51] Peter Lee, "Patents and the University," *Duke Law Journal* 63 (2013): 1 – 87, 63 – 75.

[52] Cooperative Research and Technology Enhancement Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596.

[53] This rule has been superseded by the shift to a first to file system under the America Invents Act, but prior to that time it was codified at 35 U.S.C. § 103(c).

[54] 35 U.S.C. § 200.

[55] Lee, "Patents and the University," 68 [see note 51].

[56] 35 U.S.C. § 102(b),(d) (pre-AIA version). Under these provisions, an inventor would lose the right to a patent by waiting more than a year to file a patent application after the occurrence of certain events, including publication, public use or sale of the invention, and patenting the invention in another country.

[57] *State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998); and American Inventors Protection Act of 1999, Pub. L. No. 106-113, tit. IV, 113 Stat. 1501, codifed as amended in pertinent part at 35 U.S.C. § 273.

[58] Codified at 35 U.S.C. §§ 273(a), 372(e)(1)(A),(B), and 273(c)(2).

[59] 35 U.S.C. §§ 273(e)(5)(A).

[60] 35 U.S.C. §§ 273(c)(2).